K030876

510(k) SUMMARY

Submitter:	Cynosure, Inc. 10 Elizabeth Drive Chelmsford, MA 01824
Contact:	George Cho Senior Vice President of Medical Technology
Date Summary Prepared:	March 19, 2003
Device Trade Name:	Cynosure TriActive Therapeutic Massage System
Common Name:	Therapeutic Massager
Classification Name:	Therapeutic Massager 21 CFR 890.5660
Equivalent Device:	LPG Therapeutic Massager and Vibrator
Device Description:	The TriActive system utilizes three different mechanisms simultaneously: pulsatile vacuum massage, diode laser for deeper tissue warming to enhance micro-circulation, and superficial skin cooling.
Intended Use:	The TriActive is indicated for minor muscle aches, pain, and spasm. It is also indicated for improvement in local circulation and reduction in the appearance of cellulite.
Comparison:	It has the same indications as the predicate device except, it further contains a laser device for deeper tissue warming.
Nonclinical Performance Data:	none
Clinical Performance Data:	none
Conclusion:	The TriActive Therapeutic Massage System is another safe and effective device for the indications.
Additional Information:	none

EXHIBIT F

Indications for Use

501(k) Number (if known): K030876

Device Name: Cynosure TriActive Therapeutic Massage System

Indications For Use:

- Relieves minor muscle aches and pains
- Relieve muscle spasm
- Temporary Improvement in local circulation
- Temporarily reduces the appearance of cellulite

Prescription Use _____ AND / OR Over-the-Counter Use ✓
(Per 21 CFR 801 Subpart D) (Per 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K030876

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 3 0 2005

Mr. George Cho
Senior Vice President
Cynosure, Inc.
10 Elizabeth Drive
Chelmsford, Massachusetts 01824-4145

Re: K030876
Trade/Device Name: Cynosure Triactive Therapeutic Massage System
Regulation Number: 21 CFR 890.5500, 21 CFR 890.5660
Regulation Name: Infrared Lamp, Therapeutic massager
Regulatory Class:II
Product Code: ILY, ISA
Dated: December 18, 2003
Received: December 19, 2003

Dear Mr. Cho:

This letter corrects our letter of January 22, 2004 regarding the regulation name, regulatory class and product code of the Cynosure Triactive Therapeutic Massager.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

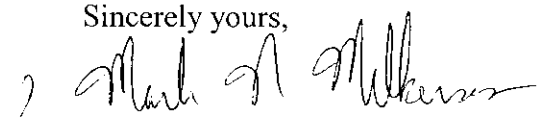
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure